2204 Wilborn Avenue South Boston, Virginia 24592 434-517-3100



AN AFFILIATE OF HALIFAX REGIONAL HEALTH SYSTEM

October 16, 2006

Mr. Mike Perkins United States Nuclear Regulatory Commission Division of Nuclear Materials Safety Region I 475 Allendale Road King of Prussia, PA 19406

Br. 1

Reference:

Add Authorized User

Add site

Dear Mr. Perkins:

03015012

We would like to add Habib F. Bassil, M.D., as an authorized user to out license #45-18401-01. Our Radiation Safety Committee makes this recommendation for 10 CFR 35.200 use.

Enclosed please find the following documents as it relates to Dr. Bassil:

- NRC Form 313A Habib Bassil with Frank Bloe preceptor
- NRC Form 313A Habib Bassil with Richard D. Goulah, M.D., preceptor
- Letter re: Habib Bassil from Richard D. Goulah, M.D.

Also, we would like to add an address of use to our license #45-18401-01. The use of this space will be limited to 35.200 radionuclides whose ordering, receipt, possession, use, and disposal will be in keeping with our current license. A layout diagram for this space is attached. This space is located on our campus and the address is 2232 Wilborn Avenue, South Boston, Virginia 24592.

These actions have a direct bearing on the provision of cardiac care at our facility. Anything you may do to expedite this would be greatly appreciated. Should you have any questions, please contact Lewis R. Rash at (434) 517-3633.

Sincerely,

Thomas S. Kluge

Chief Operating Officer

TSK:cbs

Enclosure

Radiation Safety Committee 10/13/2006

Present Dennis Stanley, M.D., AU
Lewis Rash, RSO
Tom Kluge, Administration
Jimmy Childrey, Radiology Director
Patricia Thomas, Nursing
Karen Shotwell, Cardiac Cath

Minutes of the previous (9/19/2006) meeting were approved.

- After review and discussion the committee on proper motion and second unanimously carried to approve a new site for use of material under our NRC license.
- After review and discussion the committee on proper motion and second unanimously carried to approve the addition of Habib F. Bassil, M.D. as an authorized user for 10 CFR 35.200.

Meeting adjourned at 1225 HRS.



Richard D. Goulah, MD H. F. Bassil, MD R. C. Harmer, MSN, FNP Jennifer N. Johnson, PA-C

> Physicians Pavilion 2232 Wilborn Avenue, Suite A South Boston, Virginia 24592 (434) 572-8977 fax (434) 572-2510

October 9, 2006

U.S. Nuclear Regulatory Commission

To Whom It May Concern:

I am submitting an application for licensure as an authorized used as defined under 10 CFR 35.200 (limited to cardiovascular procedures). Enclosed please find my preceptor's letter, as well as NRC form 313A for training and experience.

Thank you for your attention to this matter.

Sincerely,

Habib F. Bassil, M.D., FACC

NRC FORM 313A

10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2008

PART I -- TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35).

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Habib F. Bassil, M.D. Proposed Authorized User 35.200

 For Physicians, Podiatrists, Dentists, Pharmacists – State or Territory Where Licensed Virginia

3. CERTIFICATION

- a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)
- b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(e); 35.290(e)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(e); or 35.690(e).
- c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.

Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

- 4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS
- a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)
- b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSR	OOM AND LABORATORY TRAI	NING (optional for Medi	cal Physicists)
Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	See Separate Form 313A		
Radiation Protection	See Separate Form 313A		
Mathematics Pertaining to the Use and Measurement of Radioactivity	See Separate Form 313A		
Radiation Biology	See Separate Form 313A		
Chemistry of Byproduct Material for Medical Use	See Separate Form 313A		
OTHER			

NRC FORM 313A (10-2005) ME

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION						
Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience			
Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys	Richard D. Goulah, M.D.	Halifax Regional Health Lic. #45-18401-01 Halifax Heart (Oddysy	04/2003 to 9/2006 260 Hrs.			
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper		Imaging) Lic. #45-25516-01	04/2003 to 9/2006 70 Hrs.			
operation of survey meters	Richard D. Goulah, M.D.	. "	04/2003 to 9/2006 180 Hrs. *			
Calculating, measuring and safely preparing patient or human research subject dosages	Richard D. Goulah, M.D.	"	04/2003 to 9/2006 180 Hrs.			
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Richard D. Goulah, M.D.	"	04/2003 to 9/2006 90 Hrs.			
Using procedures to safely contain spilled radioactive material and using proper decontamination procedures	Richard D. Goulah, M.D.	u	04/2003 to 9/2006 110 Hrs.			
Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the		·				
eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	Richard D. Goulah, M.D.	" TOTAL Hrs.>700	04/2003 to 9/2006 10 Hrs.			

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Supervising	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Tc-99m	Diagnostic 35.200		Richard D. Goulah, M.D.	Same as 6.a. above	04/03 to 9/06
					>1610 cases
					using Tc-99m

		1			1

	ORM 313A				REGULATORY COMMISSION
(10-2005)	MEDICAL USE TRAINING AN	ID EXPERIENC	E AND PRECEPTO	R ATTESTATION	(continued)
	10. SUPERVISING II	NDIVIDUAL I	DENTIFICATION AN	ID QUALIFICATION	ONS
individ	raining and experience indicated abov dual is needed to meet requirements	ve was obtained in 10 CFR Part	I under the supervision 35, provide the follow	on of (if more than wing information fo	ı one supervising or each) :
Α	A. Name of Supervisor	B. Supervise	or is:		
Ri —	Richard D. Goulah, M.D.	✓ Auth	horized User	Authorized	l Medical Physicist
-		Rad	diation Safety Officer	Authorized	l Nuclear Pharmacist
С	C. Supervisor meets requirements of	Part 35, Sectio	n(s) 35.290		·
	for medical uses in Part 35, Section	on(s) 35.200			
D	D. Address	 ,		E. Materials L	icense Number
	2204 Wilborn Ave. South Boston, Virginia 24592			. 45.4	-
	South Doston, Anguing 2 1002	14		45-10	8401-01
Note:	: This part must be completed by the experience, obtain a separate precedurements in 35.590 or Part 35,	ne individual's pro ceptor statemen	nt from each. This pa	n one preceptor is	necessary to document to meet training
	est the individual named in Item 1:		•		
11a. ✓	has satisfactorily completed the	e reauirements i	n Part 35, Section(s)	and Paragraph(s)	, 35.290 ,
Y	as documented in section(s) 6.		of this form.	GIIG I W. S. J	-
	Select one	•••••	_		••••••••••
	meets the requirements in3 types of use, as documented in			(1)(ii)(G)	€90(c) for
11c.	has achieved a level of compete	•		•	• •
	has achieved a level of compete	ency sufficient to		ently as an authoriz uses (or u	
	has achieved a level of radiation Officer for a medical use license		dge sufficient to funct	tion independently	as a Radiation Safety
11d.	A				
	I am an Authorized Nuclear Pharma	acist; or		Safety Officer; Of	
	I meet the requirements of		section	n(s) of 10 CFR Part	1 35
	or equivalent Agreement State requ			AU or AMF	Р
	for the following byproduct materia	ıl uses (or units)	<i>j</i> :		
A. Ac	Address	*************	E	B. Materials Licens	ise Number
	~		~		
." ŇÁMF	ME OF PRECEPTOR (print clearly)	D SIGNAT	URE - PRECEPTOR	20	E. DATE
Rich	hard D. Goulah, M.D.	Tia.	D 11/4 / Say	.dl/_u0	10-6-06

Kichardh Guell MD 10-6-06
PAGE 4

	6c. TR	AINING F	OR SECTIONS	35.50(e), 35.51(c), 35.	590(c), or 35.690(c)
	Training Element			f Training *	Location and Dates
vendor tra	ining.	•			1(c), and 35.690(c)), didactic, or
7. FOR	MAL TRAINING	Physici	ans (for uses ur	nder 35.400 and 35.6	00) and Medical Physicists
•	Degree, Area of Study or Residency Program		of Program and cation with responding Materials nse Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
	8. RADIATIO	ON SAFE	TY OFFICER (R	SO) ONE-YEAR FU	LL-TIME EXPERIENCE
YES N/A			e radiation safet	y experience (in areas the RSO for License	identified in item 6a) under supervison. No
	9. MEDICAL	PHYSICI	ST ONE-YEAR	R FULL-TIME TRAINII	IG/WORK EXPERIENCE
YES N/A	(35.961) or medical	al physics	(35.51) under th	ne supervision of	a) in therapeutic radiological physics norized Medical Physicists (35.51);
	who is a medical p	onysicist (35.901) of meets	requirements for Aut	ionzed Medical Fifysicists (33.51),
				and	
		d 1 year of full-time work experience (at location providing radiation therapy services descripics identified in item 6a) for (specify use or device)			
YES N/A	•		•	•	g radiation therapy services described

	THE PROPERTY OF THE PROPERTY O
NRC FORM 313A	U.S. NUCLEAR REGULATORY COMMISSION
(10-2005)	

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 10/31/2008

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

PART I -- TRAINING AND EXPERIENCE

Descriptions of training and experience must contain sufficient detail to match the training and experience Note: criteria in the applicable regulations (10 CFR Part 35).

Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements 1. (e.g., 10 CFR 35.50)

Habib F. Bassil, M.D.

For Physicians, Podiatrists, Dentists, Pharmacists - State or Territory Where Licensed 2.

3. CERTIFICATION

- Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if a. applying under other subparts.)
- Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); b. 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).
- Provide completed Part II Preceptor Attestation, Items 11a through 11d. c.

Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

- 4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICIST (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS
- Provide a copy of the license or broadscope permit listing the current authorization and (b) or (c).
- Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to b. meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)						
Description of Training	Location	Clock Hours	Dates of Training			
Radiation Physics and Instrumentation	Associates in Medical Physics, LLC 5288 Transportation Blvd Cleveland, OH 44125	35	September 8-15, 2006			
Radiation Protection	н	27	u			
Mathematics Pertaining to the Use and Measurement of Radioactivity	11	6	и			
Radiation Biology	"	5	u			
Chemistry of Byproduct Material for Medical Use	" 7*		"			
OTHER	• Includes hands on experience in Mo-99/Tc-99m generator elution, kit preparations and alumina breakthrough analysis, while being supervised in a radiopharmacy.					

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

MEDICAL USE TRAINING AND EXPENIENCE AND PRECEIT ON A TESTATION (CONTINUED)							
6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), OR 35.690(c)							
	Trainir	ng Element	Type of Tra	ining*		Location and Dates	
reg emer	gulatory r rgency pr se allowe	radiation safety, requirements and rocedures for types od in 10CFR35.290 CFR35.50(e).				As described in Item 5 above: Associates in Medical Physics, LLC 5288 Transportation Blvd Cleveland, OH 44125 September 8-15, 2006	
	vendor t	training.				(c), and 35.690(c)), didactic,	
	7	7. FORMAL TRAIN	ING Physicians (for t	uses under 35.400 a	ind 3	5.600) and Medical Physicists	
Degree, Area of Study or Residency Program		or	Name of Program and Location with Corresponding Materials License Number	Dates		Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)	
			·	·			
_			ION SAFETY OFFICER (RS	The state of the s			
	YES		ar of full-time radiation safe tl			entified in item 6a) under supervision	
⊠	N/A	J	ti			,	
		9. MEDIC	CAL PHYSICIST ONE-YE	AR FULL-TIME TRAI	NING	WORK EXPERIENCE	
	YES	Completed 1-year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of					
Ø	N/A	who is a medical	al physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);				
				and			
	YES		ed 1-year of full-time work experience (at location providing radiation therapy services described opics identified in item 6a) for (specify use or device)				
	N/A	under the superv meets requirem					

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	FORM 313A	U.S. NUC	LEAR REGULATORY COMMISSION
{10-20	MEDICAL USE TRAINING AND EXPERIENCE	CE AND PRECEPTOR ATTE	STATION (continued)
	10. SUPERVISING INDIVIDUAL		
	raining and experience indicated above was obtained dual is needed to meet requirements in 10 CFR 35, p		
A.		pervisor is:	
		Authorized User	☐ Authorized Medical Physicist
C.	□ F Supervisor meets requirements of Part 35, Sectio	Radiation Safety Officer	☐ Authorized Nuclear Pharmacist
	for medical uses in Part 35, Section(s)		
D.	Address	E. Materials License Num	nber
	PART II - PREC	EPTOR ATTESTATION	
Note:	This part must be completed by the individual's p document experience, obtain a separate precepto training requirements in 35.590 or Part 35, Subpa	r statement from each. Th	
	st the individual named in Item 1:		
11a. ⊠	has satisfactorily completed the requirements in F	Part 35 Section (s) and Pa	ragraph(s) 35 290(s)(1)(i)
	as documented in section(s) 5,6c of this for		
11b.	Select one		
	meets the requirements in \square 35.50(e) \square 35.51(c types of use, as documented in section(s) of		35.690(c) for
⊠ N/A	A		
11c.			
	has achieved a level of competency sufficient to		-
<u>. </u>	has achieved a level of competency sufficient to	anction independently as	
	has achieved a level of radiation safety knowledg Officer for a medical use licensee; or		
⊠ N/A	· · · · · · · · · · · · · · · · · · ·		
11d.			
	l am an Authorized Nuclear Pharmacist; or	□ I am a Radiation Saf	fety Officer; or
	I meet the requirements of		CFR Part 35
	or equivalent Agreement State requirements to be for the following byproduct material uses (or unit	•	
A.	Address 5288 Transportation Blvd Cleveland, OH 44125	В.	Materials License Number 34-26645-02
C.	NAME OF PRECEPTOR (print clearly) D. SIC Frank Bloe	SNATURE PRECEPTOR	E. DATE September 15, 2006

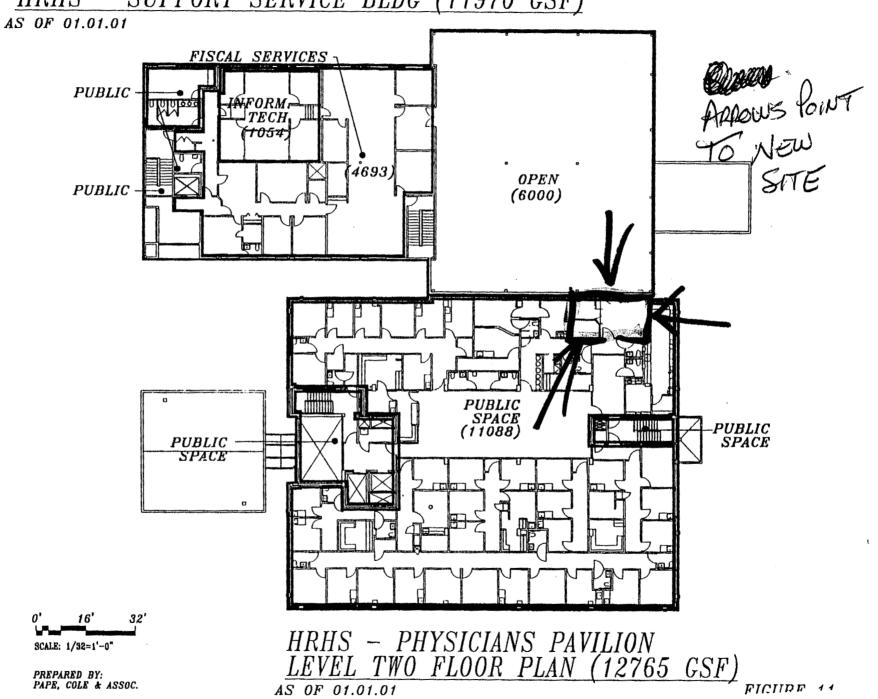
		MEDICAL USI	TRAINING AND EXPERIE	NCE AND PRECEPTO	OR ATTESTATION (continued)			
		6c. TR	AINING FOR SECTIONS 3	5.50(e), 35.51(c), 3	5.590(c), OR 35.690(c)			
	Train	ing Element	Type of Tra	aining *	Location and Dates			
re eme	egulatory ergency p ise allow	radiation safety, requirements and procedures for types ed in 10CFR35.290 CFR35.50(e).	Didactic training in the form of lecture and hands on radiopharmacy experience as described in Item 5 above on this NRC Form 313A.		As described in Item 5 above: Associates in Medical Physics, LLC 5288 Transportation Blvd Cleveland, OH 44125 September 8-15, 2006			
	*Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training. 7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists							
Degree, Area of Study or Residency Program		or	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)			
		8. RADIATI	ON SAFETY OFFICER (RS	O) ONE-YEAR FUL	L-TIME WORK EXPERIENCE			
	YES				eas identified in item 6a) under supervision			
⊠	N/A	of	tr	ne RSO for License N	lo			
		9. MEDIC	CAL PHYSICIST ONE-YE	AR FULL-TIME TRAIN	NING/WORK EXPERIENCE			
	YES	Completed 1-year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of						
×	N/A	who is a medical	nedical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);					
				and				
	YES				iding radiation therapy services described			
	N/A	under the supervision of who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device)						

SUPPLEMENT A U.S. NUCLEAR REGULATORY COMMISSION TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER 2. FOR PHYSICIANS, STATE OR 1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER TERRITORY WHERE LICENSED Habib F. Bassil, M.D. 3. CERTIFICATION MONTH AND YEAR CERTIFIED CATEGORY SPECIALTY BOARD В 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES TYPE AND LENGTH OF TRAINING LOCATION AND DATE(S) OF TRAINING FIELD OF TRAINING CLOCK HOURS IN CLOCK HOURS OF LECTURE OR SUPERVISED LABORATORY ON-THE-JOB **EXPERIENCE** 80 Hour Nuclear Licensing Course for Physicians held by Associates in Medical a. RADIATION PHYSICS AND Physics LLC in Cleveland, Ohio on the INSTRUMENTATION 35 following dates: September 8-15, 2006 27 b. RADIATION PROTECTION c. MATHEMATICS PERTAINING TO 6 THE USE AND MEASUREMENT OF RADIOACTIVITY 5 d. RADIATION BIOLOGY e. RADIOPHARMACEUTICAL 4 3 CHEMISTRY 5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience) ISOTOPE TYPE OF USE LOCATION

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE mCi USED AT ONE TIME LOCATION CLOCKS HOURS TYPE OF USE

HRHS - SUPPORT SERVICE BLDG (11970 GSF)



Schulb Still 1.84 I WAGIN'G ROOM Lewis 36. Schechte, Rosh 2-6 6

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